REMARKS

Applicant has amended claims 16 and 17 to recite methods that "consist of" particular steps. Support for these amendments are found on page 10, lines 12-15.

35 U.S.C. § 103(a) Rejections

Claims 1, 2, 5-7 and 10 stand rejected under 35 U.S.C. 103(a) for purportedly being unpatentable over Komer U.S. Patent No. 5,773,422 ("Komer") in view of Huet et al., U.S. Patent No. 6,482,425, ("Huet"). Applicant respectfully disagrees and in view of the following remarks request that the Examiner reconsider and withdraw the rejection.

The Examiner contends that Komer discloses a pharmaceutical composition comprising ivermectin, propylene glycol and poly sorbate 80 and benzyl alcohol but does not disclose the addition of ethanol or isopropanol. However, Applicant's claimed pharmaceutical solutions "consists essentially of" ivermectin, propylene glycol and poly sorbate 80 and benzyl alcohol and do not require N-methylpyrrolidone or 2-pyrrolidone. In contrast, each and every pharmaceutical solution disclosed by Komer also includes either N-methylpyrrolidone or 2-pyrrolodone as necessary components to dissolve the invermectin. As such, Komer fails to teach or suggest the claimed invention, which is limited to the claimed essential ingredients plus any compounds present

in impurity level concentrations. Huet does not compensate for Komer's deficiencies.

The Examiner contends that Huet teaches that benzyl alcohol, ethanol and isopropanol can interchangeably be used in invermectin containing compositions. But Huet fails to teach a pharmaceutical composition limited to the claimed essential ingredients and as such one of skill in the art would have no motivation to remove N-methylpyrrolidone from Komer's compositions. As such, the combination of Komer and Huet fails to render the claimed invention obvious.

Claims 10-12, 15 and 16 stand rejected under 35 U.S.C. 103(a) for purportedly being unpatentable over Komer. Applicant respectfully disagrees and in view of the following remarks requests that the Examiner reconsider and withdraw the rejection of the claims.

Claim 10 depends on claim 6, which requires that the pharmaceutical solution consists essentially of Ivermectin, 10-99% v/v isopropyl alcohol, propylene glycol and polysorbate 80. Komer only teaches pharmaceutical solutions using N-methylpyrrolidone or 2-pyrrolodone as a primary solvent to dissolve Ivermectin. The Examiner cites Examples 14 and 17 as disclosing a formulation comprising ivermectin, propylene glycol and polysorbate 80. The Examiner acknowledges Komer does not disclose the amounts of propylene glycol and polysorbate 80 encompassed by Applicant's claims, but contends a person of

ordinary skill in the art would have been motivated to add additional amounts of propylene glycol and polysorbate 80 to the composition without adversely affecting the composition. However, Applicant's claimed pharmaceutical solutions consist essentially of particular components and do not require N-methylpyrrolidone or 2-pyrrolidone. In contrast, each and every pharmaceutical solution disclosed by Komer also includes either N-methylpyrrolidone or 2-pyrrolidone as necessary components to dissolve the invermectin. Furthermore, Applicant's claimed pharmaceutical compositions comprise 10-99% isopropyl alcohol, in addition to propylene glycol and polysorbate 80. Komer's Examples 14 and 17 and Col. 3, lines 6-45 do not disclose isopropyl alcohol. As such, Komer fails to teach or suggest Applicant's claimed invention, which consists essentially of ivermectin, 10-99% v/v isopropyl alcohol, propylene glycol and polysorbate 80 plus any compounds present in impurity level concentrations. Accordingly, Applicant respectfully requests that the Examiner withdraw the rejection of claims 10-12, 15 and 16 under 35 U.S.C. 103 based on Komer.

Regarding claims 11, 12, and 15, as discussed above, each and every pharmaceutical solution disclosed by Komer also includes either N-methylpyrrolidone or 2-pyrrolidone as necessary components to dissolve the invermectin. Applicant's claimed pharmaceutical solution consists essentially of particular components and does not require N-methylpyrrolidone or 2-pyrrolidone. As such, Komer fails to teach or suggest the claimed invention and

Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of claims 11, 12 and 15 under 35 U.S.C. 103 in view of Komer.

Regarding the rejection of claim 16, as discussed above, each and every formulation disclosed by Komer was prepared using either N-methylpyrrolidone or 2-pyrrolidone as necessary components to dissolve the invermectin. Applicant's method as claimed consists of particular steps that do not include using either N-methylpyrrolidone or 2-pyrrolidone as necessary components to dissolve the invermectin and Komer does not suggest excluding the step of dissolving ivermectin in N-methylpyrrolidone or 2-pyrrolidone from the method. As such Komer does not render Applicant's invention obvious and Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of claim 16 under 35 U.S.C. 103 in view of Komer.

Claims 17, 18, 22 and 23 stand rejected under 35 U.S.C. 103(a) for purportedly being unpatentable over Komer in view of Lacy et al. U.S. Patent No. 5,645,856 ("Lacy"). Applicant respectfully disagrees and in view of the following remarks and amendments to the claims requests that the Examiner reconsider and withdraw the rejection of the claims.

As discussed above, each and every pharmaceutical solution disclosed by Komer was prepared using either N-methylpyrrolidone or 2-pyrrolidone as necessary components to dissolve the invermectin. Applicant's methods as claimed consist of particular steps that do not include using either N-

methylpyrrolidone or 2-pyrrolidone to dissolve the invermectin and Komer does not suggest excluding N-methylpyrrolidone or 2-pyrrolidone from the method. Lacy does not compensate for Komer's deficiencies. Lacy merely provides a list of sweeteners (Col. 14, lines 2-3). As such Komer alone or in combination with Lacy does not render Applicant's invention obvious. Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of claim 16 under 35 U.S.C. 103(a) over Komer in view of Lacy.

Claims 19-21 stand rejected under 35 U.S.C. 102(b) for purportedly being anticipated by, or in the alternative, under 35 U.S.C. 103(a) for purportedly being obvious over Komer.

The Examiner contends that if there are differences in amounts of the components present in the Komer formulations and the claimed compositions, such difference would appear minor in nature and the claimed compositions would be prima facie obvious from Komer's disclosure. Applicant respectfully disagrees.

The Examiner acknowledges that the claims are limited to the terminology "consisting essentially of" but contends that Applicant failed to show that N-methylpyrrolidone present in the formulation of Example 14 and 17 would materially affect the basic and novel characteristics of the claimed invention (Office Action page 4). However, Komer's statements of the unexpected solubility of avermectins in N-methylpyrrolidone and the advantages

of including N-methylpyrrolidone in his invermectin formulations (Col. 2, lines 47-61) demonstrate that one of skill in the art believes that N-methylpyrrolidone materially affects the basic and novel characteristics of those formulations. Therefore, one skilled in the art would also expect N-methylpyrrolidone to affect the basic and novel characteristics of the claimed invention. As such, the term "consisting essentially of" excludes N-methylpyrrolidone from the claimed invention.

Komer does not teach or suggest pharmaceutical compositions consisting essentially of ivermectin, propylene glycol and polysorbate 80 and therefore does not anticipate or render the claimed invention obvious. In view of the foregoing remarks, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of claims 19-21 under 35 U.S.C. 102(b), or in the alternative, under 35 U.S.C. 103(a) for purportedly being anticipated by, or obvious over, Komer.

CONCLUSION

Applicant believes the present paper to be a complete and thorough response to the Non-Final Office Action. In view of the foregoing amendments and remarks, the application is respectfully submitted to be in condition for allowance. Accordingly, a timely favorable action is earnestly solicited.

If there are any questions regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

If necessary to effect a timely response, this paper should be considered as a petition for an Extension of Time sufficient to effect a timely response, and please charge any deficiency in fees or credit any overpayments to Deposit Account No. 05-1323 (Docket #101918.56959C1).

Respectfully submitted,

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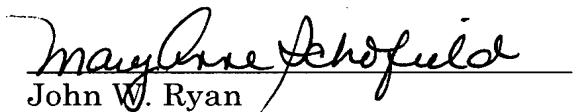

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